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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,409	Applicant(s) KATES ET AL.
	Examiner OMAR F. FERNANDEZ RIVAS	Art Unit 2129

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 04 January 2005.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5) Claim(s) ____ is/are allowed.

6) Claim(s) 1-20 is/are rejected.

7) Claim(s) ____ is/are objected to.

8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 04 January 2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-166/08)
 Paper No(s)/Mail Date 7/22/2005

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____

5) Notice of Informal Patent Application

6) Other: ____

DETAILED ACTION

1. Claims 1-20 are pending on this application.

Specification

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph **on a separate sheet** apart from any other text within the range of 50 to 150 words.

Claim Objections

3. Claims 1-20 are objected to because of the following informalities:

Independent claim 1 should begin: "**A** method for..."

Dependent claims should begin with "**The** method according to claim..."

Otherwise, the claims may be interpreted to be independent claims, other methods.

Claim 8

The claim recites: "...augmenting the input data set by **at least one** additional input variable taken from the further input data, further outcome data and/or internal output data obtained from the trained further learning-capable system". The claim should read "...augmenting the input data set by **at least one** additional input variable taken from the further **predetermined** input data **set**, further **predetermined** outcome

data **set** and/or internal output data obtained from the trained further learning-capable system.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There are two separate requirements set forth in this paragraph:

- (A) the claims must set forth the subject matter that applicants regard as their invention; and
- (B) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

The first requirement is a subjective one because it is dependent on what the applicants for a patent regard as their invention. The second requirement is an objective one because it is not dependent on the views of applicant or any particular individual, but is evaluated in the context of whether the claim is definite — i.e., whether the scope of the claim is clear to a hypothetical person possessing the ordinary level of skill in the pertinent art.

Claims are not just words listing out invention elements...they are limitations that define the fundamental claim scope. Although an essential purpose of the examination process is to determine whether or not the claims define an invention that is both novel and nonobvious over the prior art, another essential purpose of patent examination is to determine whether or not the claims are **precise, clear, correct, and unambiguous**. The uncertainties of claim scope should be removed, as much as possible, during the examination process.

Claims 1, 17 and 18

The claim recites "augmenting the input data set **and/or** the outcome data set". The claim does not specify under what conditions or how it is determined when the input data set is augmented or when the output data set is augmented or when both should be augmented. The claim also recites "training each learning-capable system using the augmented input data set and/or the augmented outcome data set". However, there is no description of how it is determined whether to use the augmented input data, the augmented output data or both to train the system. Lacking this description in the claim, the intent of these limitations in the claimed invention cannot be established and the metes and bounds of the claim are not clear to a person of ordinary skill in the arts.

Claims 17 and 18 recite limitations similar to those of claim 1 and are rejected on the same basis.

Claim 2

The claim recites “estimating propensity score data for each subject depending on its input data”. There is no antecedent basis for the limitation “each subject depending on its input data”. Nothing in the claim suggests that there will be input data for different individuals. Note that claim 1 recites a training data set corresponding to a number of subjects comprising an input data set and an output data set. The training data will be composed of input data and output data that correspond to a number of subjects. This does not suggest that there will be input data provided for each particular subject.

The claim also recites “augmenting the input data of each subject by its propensity score data **and/or** its stratum data”. There is no antecedent basis in the claim for stratum data. Also note that this limitation also recites the input data of each subject.

The claim recites: “assigning each subject to a stratum”. However, the claim does not describe how the subjects assigned to a stratum, is it arbitrary or is it depending on some metric? A person of ordinary skill in the arts would not be able to determine the intent of this limitation in the claim and the metes and bounds of the claim could not be established.

Claim 3

The claim recites “optimizing **the operating point** parameters for each stratum”. There is insufficient antecedent basis for the operating point in the claim. Moreover, a stratum seems to be a class and therefore it is not clear how an **operating point** can be

associated to a class or stratum. A stratum does not operate on data or performs any function itself.

Claim 4

The claim recites: "such that the median of **all output data** vanishes **for each stratum**". There is insufficient antecedent basis for output data in the claim. Moreover, what is this output data? How is it produced? Are the stratum somehow producing this output data? How are they producing this data? Data relating to what? It is not clear what the intent of this limitation is in the claimed invention and the metes and bounds of the invention cannot be established.

Claim 5

The claim recites "the augmenting step comprises the step of: generating a plurality of augmented training data sets by augmenting **the input data set** using a predetermined statistical model". However, claim 1 does not require the input data set to be augmented and it may not even be used in training the system. Since claim 1 recites that either the input data set or the output data set are augmented, the intent of this limitation and its effect on the overall invention is not clear.

Claim 6

It is not clear if this is supposed to be an independent claim that incorporates the limitations of claim 5 or a dependent claim. Note that claim 1 says at least one learning

capable system. Therefore there may only be one learning capable system. Claim 6 says at least two learning capable systems.

The claim recites determining characteristics of the **distributions of the scores for each subject**. There is insufficient antecedent basis for this limitation in the claim. Note that the only score computed is for the learning-capable systems and there is no distribution being calculated in the claim.

Claims 7 and 19

The claims recite "the input data set is augmented using a generalized Markov chain Monte-Carlo method". However, claim 1 recites that either the input data set or the outcome data set are augmented. Therefore the claim does not require the input data set to be augmented or to even be used in training the system. The intent of this limitation and its effect on the invention is not clear and therefore the metes and bounds of the invention is not clear.

Claim 8

The claim recites: augmenting the input data set by at least one additional input variable taken from the further input data, further outcome data and/or internal output data obtained from the trained further learning-capable system. It is not clear how the input data set (assuming that this refers to the input data set of claim 1) can be augmented using this further input data, further output data or internal output data since

the claim does not state where this further data (training, input and outcome) is received from or even that this further input data are of the same type.

Claim 9

The claim recites the additional input variables comprise **all further input data and all further outcome data of a subset of subjects of the further training data set**. There is insufficient antecedent basis for this limitation in the claim since there is nothing in the claims about this further training data set being composed of sets of data about particular subjects.

Claim 10

The claim recites "the outcome data of the training data set is time-dependent and the augmenting step comprises **pre-transforming the time variable of the training data set** in such a way that **the hazard rate** with respect to a **predetermined outcome** is a predetermined function of the time variable". There is insufficient antecedent basis for the time variable of the training data. Moreover, it is the outcome data that is time dependent. There is also no antecedent basis for the hazard rate. Moreover, if the time variable is associated to the training data, how is it related to the outcome data to determine this hazard rate?

Claim 11

The claim recites "**Method for using** a learning-capable system trained according to the method of claim 1 using the input data of a subject, characterized in that the outcome is corrected with respect to a predetermined reference subject". This seems to be an independent claim that merely recites an intended use for the invention of claim 1. Moreover, there does not seem to be anything in the claim that actually says how the method of claim 1 is being used or what it is used for. How is this input data of a subject used or even collected? How does the invention use the input data of a subject, since claim 1 only uses training data to train the system?

There is also no antecedent basis for "the outcome". Moreover, what is this outcome? How is it produced?

Claim 12

It is not clear if this claim is supposed to be an independent claim or a dependent claim (a method of using a method?).

The claim recites: "the input data of a subject". There is insufficient antecedent basis for this limitation in the claim.

Claim 13

The claim recites: "Method to create a composite training data set, in particular for training a learning-capable system according to the method of claim 1, comprising the steps of: providing an aggregated evidence data set, disaggregating the aggregated

evidence data set to obtain a disaggregated training data set with virtual subjects, and merging the disaggregated training data set with a further training data set". What does it means to disaggregate an aggregated evidence data set? What does this disaggregating does to the aggregated data set? How does the limitations in this claim limit the limitations of claim 1? How is any of the data in this claim used in the method of claim 1? There does not seem to be any correlation or functional relationship between the limitations of claim 13 and claim 1 and therefore the intent of the limitations of claim 13 cannot be established. A person of ordinary skill in the arts would not be able to determine the metes and bounds of the invention. Note that claims 14 and 15 depend on 13 and the limitations contained therein also lack any correlation or functional relationship to the limitations of claim 1.

Claim 14

The claim recites "the merging step comprises the step of choosing a real training data set as the further training data set". Where is this "real training data set" obtained from? How is it chosen? What is a "real training data set"? Does this means that there are other data sets that are not real and are imaginary or non-existent? The intent of this limitation is not clear and therefore the metes and bounds of the claimed invention cannot be established.

Claims 15 and 20

The claims recite "the disaggregation step comprises the step of assigning at least a value of one auxiliary variable to each virtual subject of the disaggregated training data set". However, there is no description in the claim as to how these auxiliary variables are assigned or for what purpose these variables are assigned.

Claim 16

The claim recites: "the predetermined training data set is provided by: providing an aggregated evidence data set, disaggregating the aggregated evidence data set to obtain a disaggregated training data set with virtual subjects, and merging the disaggregated training data set with a further training data set". It is not clear how the training data set is "provided" or exactly what is being provided. There is no clear correlation between the limitations of claim 16 and claim 1. Simply stated, how is the training data set of claim 1 being "provided" by any of the limitations of claim 16?

Examiner's Note: It is noted that the claims are mostly composed of non-functional descriptive material. The claims merely cite limitations that do not seem to produce any functional effect on the claimed invention. Therefore, the intent of the limitations in the claims is not clear (how do they affect the functionality of the invention?) and the metes and bounds of the claimed invention are not clear to a person of ordinary skill in the arts.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The portions of the opinions in State Street and AT&T relying **solely** on a "useful, concrete and tangible" result analysis should no longer be relied on. *Ex parte Bilski, Appeal No. 2007-1130 (Fed. Cir. October 30, 2008)*.

The court has said that there's a two-pronged test to determine whether a **software of business method process** patent is valid: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. In other words, pure software or business method patents that are neither tied to a specific machine nor change something into a different state are not patentable. *Ex parte Bilski, Appeal No. 2007-1130 (Fed. Cir. October 30, 2008)*.

Furthermore, the preamble is not given any patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. *Kropa v. Robie, 88 USPQ 478 (CCPA 1951)*. An intended use clause found in the preamble is not afforded the effect of a distinguishing limitation unless the body of the claim sets forth structure which refers back to, is defined by, or otherwise draws life and breath from the preamble. *In re Casey, 152 USPQ 235 (CCPA 1967)*.

Claims 1-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. For a method (or process) claim to be statutory under 35 USC 101, the method must be tied to another statutory class (such as a particular apparatus) or transform underlying subject matter (such as an article or materials) to a different state or thing. Therefore, the claim must positively recite the apparatus that accomplishes the method steps or positively recite the subject matter that is being transformed.

Claims 1-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The computer system must set forth a practical application of judicial exception to produce a real-world result. Benson, 409 U.S. at 71-72, 175 USPQ at 676-77. The invention is ineligible because it has not been limited to a substantial practical application.

For a claimed invention to be statutory the claimed invention must produce a useful, concrete, and tangible result. As the Supreme Court has made clear, " [a]n idea of itself is not patentable," *Rubber-Tip Pencil Co. v. Howard*, 20 U.S. (1 Wall.) 498, 507 (1874); taking several abstract ideas and manipulating them together adds nothing to the basic equation. *In re Warmerdam*, 31 USPQ2d 1754 (Fed. Cir. 1994).

For a claimed invention to be statutory under 35 U.S.C. 101, the claims must provide a tangible result, and there must be a practical application, by either: 1) transforming (physical thing) or 2) by having the FINAL RESULT (not the steps) achieve or produce a useful (specific, substantial, AND credible), concrete (substantially repeatable/non-unpredictable), AND tangible (real world/non-abstract) result.

A claim that recites a computer that solely calculates a mathematical formula is not statutory.

In the present case, claim 1 describes a method for training a learning-capable system. However the claim fails to produce a useful result because the claimed subject matter fails to sufficiently reflect at least one practical utility set forth in the descriptive portion of the specification. More specifically, while the described practical utility (utilities) is (are) directed to the fields of prognosis, risk assessment, intervention/treatment selection and treatment outcome selection for a patient (as described at e.g., paragraph 2 of the PGPUB of the instant application), the claimed subject matter relates ONLY to training the learning capable system with unspecified data, since the claim does not specify any particular type or nature of data; nor does it specify how or from where this data is obtained or what the data represents. The claim does not sufficiently reflect the application described in the specification and is not limited to any substantial and specific practical application.

The claim also fails to produce a concrete result because the claimed subject matter fails to be limited to the production of an assured, repeatable result. More specifically, the claimed subject matter is not repeatable because the claim recites: "augmenting the input data set **and/or** the outcome data set, and training each learning-capable system using the augmented input data set **and/or** the augmented outcome data set". However, the claim does not specify on what situation or on what basis invention will decide to either augment the input data set or the outcome data set or both. The claim does not specify when or under what conditions the augmented input

data or the augmented output data or both are used to train the neural network. Lacking this description in the claim, these steps seem to occur arbitrarily with no restriction and therefore the invention is not guaranteed to produce the same results given the same inputs.

Claim 1 also fails to produce a tangible result because the claimed subject matter fails to produce a result that is limited to having real world value rather than a result that may be interpreted to be abstract in nature as, for example, a thought, a computation, or manipulated data. More specifically, the claimed subject matter provides for **training a system with unspecified data**. This produced result remains in the abstract and, thus, fails to achieve the required status of having real world value. The claim encompasses training a system with unspecified, abstract data producing a system that operates on abstract data that has no specific purpose or use.

The courts have also held that a claim may not preempt ideas, laws of nature or natural phenomena. The concern over preemption was expressed as early as 1852. See Le Roy v. Tatham, 55 U.S. (14 How.) 156, 175 (1852) ("A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right."); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 132, 76 USPQ 280, 282 (1948).

Accordingly, one may not patent every "substantial practical application" of an idea, law of nature or natural phenomena because such a patent "in practical effect would be a patent on the [idea, law of nature or natural phenomena] itself." "Here the "process" claim is so abstract and sweeping as to cover both known and unknown uses

of the BCD to pure-binary conversion. The end use may (1) vary from the operation of a train to verification of drivers' licenses to researching the law books for precedents and (2) be performed through any existing machinery or future-devised machinery or without any apparatus." Gottschalk v. Benson, 409 U.S. 63, 71-72, 175 USPQ 673, 676 (1972).

Pre-emption of all uses of a fundamental principle in all fields and pre-emption of all uses of the principle in **only one field** both indicate that the claim is not limited to a particular application of the principle. See *Diehr*, 450 U.S. at 193 n.14 ("A mathematical formula *in the abstract* is nonstatutory subject matter regardless of whether the patent is intended to cover all uses of the formula or only limited uses.") (emphasis added).

In the present case, the invention has not been limited to any particular application and would cover any end use that could be given to a trained learning capable system, like network intrusion detection, failure detection, patient evaluation, financial risk assessment, document classification, etc. Moreover, since the claim does not specify any particular type or nature of data, nor does it specify how or from where the data is obtained or what the data represents, any type of data and any use known or unknown to man would be covered by the claim.

Claims 2-20 further limit claim 1 but fail to cure the deficiencies set forth above and are rejected on the same basis.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-9 and 11-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Barnhill et al. (US Patent #6,306,087, referred to as **Barnhill**).

Claims 1, 17 and 18

Barnhill anticipates method for training **at least one** learning-capable system (**Barnhill**: abstract; C6, L14-20; C18, L22-33; C23, L48 to C25, L47; Examiner's Note (EN): learning capable system not further defined to any specific type of system. Neural Networks are learning capable systems since they must be trained to perform a particular function) comprising the steps of:

providing a predetermined training data set corresponding to a predetermined number of subjects comprising a predetermined input data set and a predetermined outcome data set (**Barnhill**: C6, L14-44; C7, L39-61; C12, L59 to C13, L18; C18, L22-67; C21, L15 to C22, L6; EN: item 13 applies. The training data is a set of input values paired with known classification results. Moreover, it is inherent in back propagation learning to have a data set of values and the expected outcome of those values in order to determine the error between the expected output and the output produced by the network so that weights can be modified accordingly),

augmenting the input data set **and/or** the outcome data set (**Barnhill**: C7, L39-61; C12, L59 to C13, L18; C13, L28-60; C15, L1-38; C23, L48 to C25, L47; C30, claim 1; EN: item 13 applies. Augmenting not further defined to any particular process. The preprocessing of the training data is considered "augmenting" the data. Moreover, as a general matter, the grammar and intended meaning of terms used in a claim will dictate whether the language limits the claim scope. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation),

and training **each learning-capable system** using the augmented input data set **and/or** the augmented outcome data set (**Barnhill**: C7, L39-61; C12, L59 to C13, L18; C13, L28-60; C15, L1-38; C23, L48 to C25, L47; C30, claim 1).

Claim 2

Barnhill anticipates the augmenting step comprises the steps: estimating propensity score data for each subject depending on its input data (**Barnhill**: C6, L14-44; C7, L39-61; C12, L59 to C13, L18; C15, L1-38; C18, L22-67; C21, L15 to C22, L6; C23, L48 to C25, L47; Fig. 5; EN: item 13 applies. Propensity score data not further defined. Identifying the group to which each sample in the training data set belongs to is considered a propensity score. Also note the test for discriminating power and the scaling of the training data), dividing the propensity score data into at least two strata (**Barnhill**: C6, L32-44; C7, L39-61; C12, L59 to C13, L18; C13, L28-60; C15, L1-38; C23, L48 to C25, L47; EN: the groups to which the data belongs to (the diagnosis) is

strata), assigning each subject to a stratum (**Barnhill**: C6, L32-44; C7, L39-61; C12, L59 to C13, L18; C13, L28-60; C15, L1-38; C23, L48 to C25, L47; EN: each sample will belong to a group), and augmenting the input data of each subject by its propensity score data and/or its stratum data (**Barnhill**: C6, L32-44; C7, L39-61; C12, L59 to C13, L18; C13, L28-60; C15, L1-38; C23, L48 to C25, L47; Fig. 5; EN: item 13 applies. Augmenting not further defined to perform any specific modification on the data. Any modification of the training data could be considered "augmenting").

Claim 3

Barnhill anticipates the training step comprises the step of optimizing the operating point parameters for each stratum (**Barnhill**: C15, L1-38; C18, L22-67; C21, L15 to C22, L6; Fig. 5; EN: item 13 applies. Adjusting the network weights to reduce the error between the network outputs and the target values is considered optimizing the operating point parameters for the strata).

Claim 4

Barnhill anticipates the operating point parameters are optimized such that the median of all output data vanishes for each stratum (**Barnhill**: C15, L1-38; C21, L15 to C22, L6; EN: scaling the training data. Also note the diagnostic index computed for each output neuron).

Claim 5

Barnhill anticipates the augmenting step comprises the step of: generating a plurality of augmented training data sets by augmenting the input data set using a predetermined statistical model (**Barnhill**: C6, L32-44; C7, L39-61; C12, L59 to C13, L18; C13, L28-60; C15, L1-38; C23, L48 to C25, L47; Fig. 5; EN: statistical model not further defined).

Claim 6

Barnhill anticipates training at least two learning-capable systems, wherein the training step comprises the steps of: training each learning-capable system using a subset of the plurality of augmented training data sets (**Barnhill**: C6, L32-44; C7, L39-61; C12, L59 to C13, L18; C13, L28-60; C23, L48 to C25, L47), constructing scores for each outcome for each trained learning-capable system (**Barnhill**: C6, L32-44; C7, L39-61; C12, L59 to C13, L18; C13, L28-60; C23, L48 to C25, L47; C30-32, claims 1-4), and determining characteristics of the distributions of the scores for each subject (**Barnhill**: C6, L32-44; C7, L39-61; C12, L59 to C13, L18; C13, L28-60; C23, L48 to C25, L47; C30-32, claims 1-4).

Claim 7

Barnhill anticipates the input data set is augmented using a generalized Markov chain Monte-Carlo method (**Barnhill**: C23, L48 to C25, L47; C32, claim 5).

Claim 8

Barnhill anticipates the augmenting step comprises the steps of: providing a further learning capable-system and a further predetermined training data set comprising a further predetermined input data set and a further predetermined outcome data set (**Barnhill**: C6, L32-44; C6, L66 to C7, L16; C13, L28-60; C18, L22-67; C23, L48 to C25, L47; C30-32, claims 1-4), training the further learning-capable system using the further predetermined training data set (**Barnhill**: C6, L32-44; C6, L66 to C7, L16; C13, L28-60; C18, L22-67; C23, L48 to C25, L47; C30-32, claims 1-4), and augmenting the input data set by **at least one** additional input variable taken from the further input data, further outcome data **and/or** internal output data obtained from the trained further learning-capable system (**Barnhill**: C6, L32-44; C6, L66 to C7, L16; C13, L28-60; C18, L22-67; C23, L48 to C25, L47; C30-32, claims 1-4).

Claim 9

Barnhill anticipates the additional input variables comprise all further input data and all further outcome data of a subset of subjects of the further training data set (**Barnhill**: C6, L32-44; C6, L66 to C7, L16; C13, L28-60; C18, L22-67; C23, L48 to C25, L47; C30-32, claims 1-4).

Claim 11

Barnhill anticipates method for using a learning-capable system trained according to the method of claim 1 using the input data of a subject, characterized in

that the outcome is corrected with respect to a predetermined reference subject (**Barnhill**: C6, L32-44; C7, L39-61; C12, L38 to C13, L18; C18, L22—67; C21, L15 to C22, L6; EN: comparing the output to a target output and adjusting the network to correct the error).

Claim 12

Barnhill anticipates method for using at least two learning-capable systems trained according to the method of claim 7 using the input data of a subject, comprising the steps of: presenting the input data of the subject to each of the learning-capable systems and constructing a score for the output data obtained from the learning-capable systems (**Barnhill**: C6, L32-44; C7, L39-61; C12, L38 to C13, L60; C18, L22—67; C21, L15 to C22, L6; C23, L48 to C25, L47; C30-32, claims 1-4).

Claim 13

Barnhill anticipates method to create a composite training data set, in particular for training a learning-capable system according to the method of claim 1, comprising the steps of: providing an aggregated evidence data set (**Barnhill**: C6, L32-44; C7, L39-61; C12, L38 to C13, L60; C18, L22-67; C21, L15 to C22, L6; C23, L48 to C25, L47; C30, claim 1; EN: item 13 applies. Aggregated evidence data set not further defined. The training data containing values of biomarkers or data from patients corresponding to a disease is considered aggregated data), disaggregating the aggregated evidence data set to obtain a disaggregated training data set with virtual subjects (**Barnhill**: C6,

L32-44; C7, L39-61; C12, L38 to C13, L60; C18, L22-67; C19, L27 to C20,L60; C21, L15 to C22, L6; C23, L48 to C25, L47; C30, claim 1; EN: item 13 applies. Disaggregating not further defined to any specific transformation of data. Scaling the training data is considered disaggregating the evidence data. Also note the Input Data Preprocessing where the raw input data is processed to remove noisy data), and merging the disaggregated training data set with a further training data set (**Barnhill**: C6, L32-44; C7, L39-61; C12, L38 to C13, L60; C18, L22-67; C19, L27 to C20,L60; C21, L15 to C22, L6; C23, L48 to C25, L47; C30-31, claims 1 and 2).

Claim 14

Barnhill anticipates the merging step comprises the step of choosing a real training data set as the further training data set (**Barnhill**: C6, L32-44; C7, L39-61; C12, L38 to C13, L60; C18, L22-67; C19, L27 to C20,L60; C21, L15 to C22, L6; C23, L48 to C25, L47; C30, claim 1; EN: item 13 applies. Real training data set not further defined to any particular type or structure. Any other training data set could be considered a real training data set. Moreover, different data obtained from different subjects are considered real training data sets).

Claim 15

Barnhill anticipates the disaggregation step comprises the step of assigning at least a value of one auxiliary variable to each virtual subject of the disaggregated training data set (**Barnhill**: C13, L28-60; C15, L1-38; C19, L27 to C20, L65; C23, L48 to

C25, L47; C30-31, claims 1 and 2; EN: item 13 applies. Auxiliary variable not further defined to any specific type).

Claim 16

Barnhill anticipates the predetermined training data set is provided by: providing an aggregated evidence data set (**Barnhill**: C6, L32-44; C7, L39-61; C12, L38 to C13, L60; C18, L22-67; C21, L15 to C22, L6; C23, L48 to C25, L47; C30, claim 1; EN: item 13 applies. Aggregated evidence data set not further defined. The training data containing values of biomarkers or data from patients corresponding to a disease is considered aggregated data), disaggregating the aggregated evidence data set to obtain a disaggregated training data set with virtual subjects (**Barnhill**: C6, L32-44; C7, L39-61; C12, L38 to C13, L60; C18, L22-67; C19, L27 to C20,L60; C21, L15 to C22, L6; C23, L48 to C25, L47; C30, claim 1; EN: item 13 applies. Disaggregating not further defined to any specific transformation of data. Scaling the training data is considered disaggregating the evidence data. Also note the Input Data Preprocessing where the raw input data is processed to remove noisy data), and merging the disaggregated training data set with a further training data set (**Barnhill**: C6, L32-44; C7, L39-61; C12, L38 to C13, L60; C18, L22-67; C19, L27 to C20,L60; C21, L15 to C22, L6; C23, L48 to C25, L47; C30-31, claims 1 and 2).

Claim 19

Barnhill anticipates the input data set is augmented using a generalized Markov chain Monte-Carlo method (**Barnhill**: C23, L48 to C25, L47; C32, claim 5).

Claim 20

Barnhill anticipates the disaggregation step comprises the step of assigning at least a value of one auxiliary variable to each virtual subject of the disaggregated training data set (**Barnhill**: C13, L28-60; C15, L1-38; C19, L27 to C20, L65; C23, L48 to C25, L47; C30-31, claims 1 and 2).

Examination Considerations

9. Examiner has cited particular columns and line numbers (or paragraphs) in the references applied to the claims above for the convenience of the applicant. Although the specified citations are representative of the teachings of the art and are applied to specific limitations within the individual claim, other passages and figures may apply as well. It is respectfully requested from the Applicant in preparing responses, to fully consider the references in their entirety as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the Examiner. The entire reference is considered to provide disclosure relating to the claimed invention.

10. The claims and only the claims form the metes and bounds of the invention. "Office personnel are to give the claims their broadest reasonable interpretation in light

of the supporting disclosure. *In re Morris*, 127 F.3d 1048, 105455, 44USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim are not read into the claim. *In re Prater*, 415 F.2d, 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969)" (MPEP p 2100-8, c 2, I 45-48; p 2100-9, c 1, I 1-4). The Examiner has full latitude to interpret each claim in the broadest reasonable sense. Examiner will reference prior art using terminology familiar to one of ordinary skill in the art. Such an approach is broad in concept and can be either explicit or implicit in meaning.

11. Examiner's Notes are provided with the cited references to prior art to assist the applicant to better understand the nature of the prior art, application of such prior art and, as appropriate, to further indicate other prior art that maybe applied in other office actions. Such comments are entirely consistent with the intent and spirit of compact prosecution. However, and unless otherwise stated, the Examiner's Notes are not prior art but a link to prior art that one of ordinary skill in the art would find inherently appropriate.

12. Unless otherwise annotated, Examiner's statements are to be interpreted in reference to that of one of ordinary skill in the art. Statements made in reference to the condition of the disclosure constitute, on the face of it, the basis and such would be obvious to one of ordinary skill in the art, establishing thereby an inherent *prima facie* statement.

13. Examiner's Opinion: items 10-12 apply. The claims and only the claims form the metes and bounds of the invention. The Examiner has full latitude to interpret each claim in the broadest reasonable sense.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Mizuno US Patent #5,577,166

Menon et al. US Patent #5,703,964

Barnhill et al. US Patent #6,248,063

Barnhill et al. US Patent #6,306,087

Agrafiotis et al. US Patent #6,571,227

Kates et al. US PGPUB #2004/0073096

Barnhill et al. US Patent #6,789,069

Barnhill et al. US Patent #6,882,990

Chen et al. US Patent #6,917,926

Hartman et al. US Patent #7,107,253

Sumner et al. US Patent #7,107,253

Chen et al. US PGPUB #2008/0120267

15. Claims 1-20 are rejected.

Correspondence Information

16. Any inquires concerning this communication or earlier communications from the examiner should be directed to Omar F. Fernández Rivas, who may be reached Monday through Friday, between 8:00 a.m. and 5:00 p.m. EST. or via telephone at (571) 272-2589 or email omar.fernandezrivas@uspto.gov.

If you need to send an Official facsimile transmission, please send it to (571) 273-2589.

If attempts to reach the examiner are unsuccessful the Examiner's Supervisor, David Vincent, may be reached at (571) 272-3080.

Hand-delivered responses should be delivered to the Receptionist @ (Customer Service Window Randolph Building 401 Dulany Street Alexandria, VA 22313), located on the first floor of the south side of the Randolph Building.

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Examiner, Art Unit 2129
Wednesday, December 17, 2008.

/David R Vincent/
Supervisory Patent Examiner, Art Unit 2129